



California State Board of Pharmacy

400 R Street, Suite 4070, Sacramento, CA 95814

Phone (916) 445-5014

Fax (916) 327-6308

www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

ARNOLD SCHWARZENEGGER, GOVERNOR

LICENSING COMMITTEE

Hilton Burbank Airport & Convention Center

2500 Hollywood Way

Burbank, CA 91505-1019

(818) 843-6000

June 9, 2004

9:30 a.m. – 12 noon

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 5 working days prior to the meeting. Opportunities are provided to the public to address the committee on each agenda item. Board members who are not on the committee may also attend and comment.

- A. Call to Order** **9:30 a.m.**
- B. Request for Changes to CCR, title 16, sec. 1732 – 1732.7 Relating to Continuing Education (CE)**
- C. Report on the Implementation of the North American Pharmacy Licensure Examination (NAPLEX) and the California Pharmacist Jurisprudence Examination (CPJE)**
- D. Request from the Schools of Pharmacy for an Open Dialogue Regarding the Intern Requirements Specified in CCR, title 16, sec. 1728**
- E. Report on the Implementation of the Licensure Program for Pharmacies that Compound Sterile Injectable Drug Products – One-year implementation evaluation**
- F. Implementation of the Statewide Protocol for Pharmacist to Furnish Emergency Contraception**
- G. California Pharmacy Manpower Statistics – December 2003**

Adjournment

12 noon

Meeting materials will be on the board's Web site by June 2nd

AGENDA ITEM B



Discover the people and power of pharmacy...

May 12, 2004

Patricia Harris
Executive Officer
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, California 95814

Re: Request for Regulatory Changes regarding the AES Program

Dear Patty,

Beginning on January 1, 2004, the activities of the Accreditation Evaluation Service (AES) were moved from the California Pharmacists Association to the California Pharmacists Association Educational Foundation. In addition, the California Pharmacists Association Educational Foundation began doing business as the Pharmacy Foundation of California. In order to provide AES with a more descriptive and appropriate name, we are also changing the name of AES to "California Accreditation for Pharmacy Education" or CAPE.

To conform the current Pharmacy Law with these changes, we are asking the Board of Pharmacy to pursue a few minor changes to the pharmacy regulations that deal with pharmacist continuing education. At the same time, we are asking that other non-substantive changes be incorporated to reflect the current terminology and operational standards of both AES and the Accreditation Council for Pharmacy Education (ACPE). To assist the Board, we have included recommended language that incorporates these proposed changes.

A summary of the changes:

Changes made to CCR Title 16, Division 17, Article 4:

- Change the term "continuing pharmaceutical education" to "continuing pharmacy education" throughout the regulations.
- Changing AES from a "continuing education provider and coursework review component of the California Pharmacists Association" to "an accrediting agency for providers of continuing pharmacy education in California"
- Changing the role of AES and ACPE from "approvers" to "accreditors"
- Changing "ownership" of AES from CPhA to CPhA Educational Foundation DBA Pharmacy Foundation of California
- Correcting what appears to be incorrect language from "organization" to "accreditation agency".
- Changing the review/audit requirement to a minimum of once a year from a minimum of 10%.
- Changing the term "certificates of completion" to "statements of credit"
- Updating the requirement of the provider to furnish statements of credit to "all enrollee" to "participants who complete all the requirements for course completion".
- Adding that material must still be "current" in order for it to be valid for CE, rather than a blanket 3 year shelf life.

4030 Lennane Drive Sacramento, California 95834 916 779-1410

- Change the name of Accreditation Evaluation Service (AES) to California Accreditation for Pharmacy Education (CAPE).

It is our desire and intent to implement these changes as soon as possible. Please advise us if there are any problems with these proposed changes or our immediate implementation of them. If we can be of any additional assistance in seeing these changes incorporated, or if there are any questions or other concerns about this request, please call me at (916) 779-1410 ext. 323. We will assume that if we don't hear from you that this is acceptable to the Board.

Thank you for your assistance.

Sincerely,

Lynn Rolston
Executive Director

Carlo Michelotti, RPh, MPH
CEO, CPhA

CA Code of Regulations

TITLE 16. Professional And Vocational Regulations

Division 17. California State Board of Pharmacy

Article 4. Continuing Education

Article 4. Continuing Education

§1732. Definitions.

As used in this article:

(a) An accreditation agency is an organization which evaluates and accredits providers of continuing ~~pharmaceutical~~ pharmacy education, monitors the quality of their educational activities, and audits continuing education coursework.

(b) The Accreditation Council for Pharmacy Education (ACPE) is the national accrediting agency for providers of continuing ~~pharmaceutical~~ pharmacy education.

(c) The Accreditation Evaluation Service is an accrediting agency for providers of continuing pharmacy education in California. ~~is the continuing education provider and coursework review component of the California Pharmacists Association.~~

(d) A recognized provider is anyone whose qualifications as a continuing education provider have been accredited ~~approved~~ by an accreditation agency approved by the Board.

(e) An hour consists of at least 50 minutes of contact time.

NOTE

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

§1732.05. Accreditation Agencies.

(a) The following organizations are approved by the Board as ~~continuing education and accreditation agencies~~ of continuing pharmacy education:

(1) The Accreditation Council for Pharmacy Education

(2) The ~~Accreditation Evaluation Service~~ California Accreditation for Pharmacy Education of the California Pharmacists Association Educational Foundation DBA Pharmacy Foundation of California.

(b) Upon written application to the Board, any other organization will be approved by the board if:

(1) the organization submits a plan demonstrating that it has the capacity to evaluate each continuing education provider in accordance with the following criteria:

(A) Topics and subject matter shall be pertinent to the practice of pharmacy as specified in section 4232 of the Business and Professions Code and [section 1732.1\(c\)](#) of the California Code of Regulations.

(B) Each continuing education course shall have written educational goals and specific learning objectives which are measurable and which serve as a basis for an evaluation of the program's effectiveness.

(C) Speakers shall be competent in the subject matter and shall be qualified by education, training and/or experience.

(D) Each continuing education course shall have a syllabus which provides a general outline of the course. The syllabus shall contain at a minimum, the instructional objectives for each course and a summary containing the main points for each topic.

(E) When an ~~approved~~ accredited provider works with others on the development, distribution and/or presentation of continuing education programs (joint sponsorship), there shall be procedures to identify and document the functions of each participating party.

(F) Promotional materials shall meet the requirements specified in [section 1732.3\(d\)](#) of the California Code of Regulations. Advertisements shall also include at least the following:

1. the educational goals and specific learning objectives of the program.
2. the nature of the targeted audiences that may best benefit from participation in the program.
3. the speakers and their credentials.

(G) An evaluation mechanism shall be used. The mechanism shall allow all participants to assess their achievement in accordance with the program's learning objectives. Self-evaluation mechanisms may include, but are not limited to, pre- and post-testing, post-testing along with group discussion and critique of answers, patient case-study discussions and problem solving exercises. The provider shall also develop a mechanism for each participant to evaluate the continuing education course.

(H) Where the method of educational delivery does not translate into contact hours, such as home study programs and other mediated instructional approaches, there shall be procedures for the determination of hours of credit for courses. Procedures used to determine the amount of time required for participants to successfully complete the program shall be documented and defensible. Acceptable procedures include:

1. assessing the amount of time the activity would require if it were delivered in a more formal and structured live program format; or,
2. pilot testing the activity with a group of pharmacists who are representative of the target audience and ascertaining the mean average length of time for completion for only those participants who successfully complete the program; or,
3. determination by an advisory panel, consisting of individuals qualified by experience and training in the development and administration of continuing education.

(I) The provider shall be required to maintain records of each enrollee's participation in continuing education programs.

1. For live programs, acceptable documentation of participation includes attendance rosters, sign-in sheets, completed program evaluation forms, or signed verification forms.

2. For home study and other mediated instructional approaches--acceptable documentation of participation includes:

a. use of a post-testing procedure in which a pre-established proficiency level is established and certificates are awarded only upon attainment of the pre-specified minimum proficiency level;

b. in the case of study groups, the successful completion of the program may be attested to by all participants; or

c. completion and submission, by the individual participant, of a written evaluation or critique of both the program and its applicability to the participant's practice of pharmacy. The evaluation shall be of sufficient length and detail to demonstrate successful completion of the program and a reasoned consideration of its applicability to the participant's professional practice.

(2) The ~~organization~~ accreditation agency agrees to perform the following:

(A) Maintain a list of the names and addresses of the persons designated as responsible for their accredited provider's C.E. program. The accreditation agency shall require that any change in the designated responsible person's identity shall be reported to the agency within 15 days of the effective date of such change.

(B) Notify the Board of names, addresses and responsible party of each provider.

(C) Respond to complaints from the Board, providers or from California pharmacists concerning activities of any of its approved providers or their coursework.

(D) Review at least ~~a ten percent (10%) sample of coursework, as determined by the Board, but not less than~~ one course per year offered by each provider approved accredited by the agency for compliance with the agency's requirements and requirements of the Board and, on request, report the findings of such reviews to the Board.

(E) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the Board; and

(F) Verify attendance of licentiates at specific presentations upon request of the Board.

(c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in (b)(1) or to perform in accordance with the terms of its agreement as described in (b)(2) shall constitute cause for revocation of approval by the Board.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

§1732.1. Requirements for Recognized Providers

(a) Anyone seeking to provide continuing education courses as a recognized provider for California pharmacists shall apply to a Board approved accreditation agency for ~~recognition~~ accreditation as a provider prior to offering any such courses.

(b) Upon satisfactory completion of the accreditation requirements of the accreditation agency and receipt of written approval therefrom, a continuing education provider may represent itself as a California recognized provider of continuing education material for pharmacists.

(c) The provider is responsible for assuring the educational quality of its coursework. Coursework shall be relevant to the practice of pharmacy and shall be related (1) to the scientific knowledge or technical skills required for the practice of pharmacy, or (2) to direct and/or indirect patient care, or (3) to the specific management and operation of a pharmacy practice. All continuing education coursework shall be:

- (1) accurate and timely;
- (2) presented in an orderly fashion conducive to the learning process;
- (3) complete and objective, and not reflecting predominantly the commercial views of the provider or of anyone giving financial assistance to the provider;
- (4) specifically applicable and pertinent to the practice of pharmacy; and
- (5) based on stated educational goals and objectives.

(d) All providers shall furnish ~~certificates of completion~~ statements of credit to all ~~enrollees~~ participants who complete all the requirements for course completion. The ~~certificate~~ statement shall contain the name of the enrollee, name and number of the provider, title of the course, number of completed hours, date of completion, expiration date of the coursework, course number, if applicable and the name of the accrediting agency.

(e) Each recognized provider shall notify the accreditation agency, on forms approved by the board, within 15 days of the first time each new C.E. course is offered or presented

(f) All providers shall maintain records of attendance at or completion of their continuing education programs for four (4) years.

NOTE

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

§1732.2 Coursework From Non-Recognized-Providers

(a) Non-recognized providers or pharmacists may petition the Board to allow continuing education credit for specific coursework which is not offered by a recognized provider but meets the standards of relevance to pharmacy practice and educational quality, as set forth in Section subdivision (c) of section 1732.1 ~~(e)~~.

(b) Notwithstanding subdivision (a) of this section, coursework ~~Coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing~~

~~education by is accepted by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California California State Board of Dental Examiners as meeting their requirements, which meets the standards of relevance to pharmacy practice, and which is not offered by an approved provider as set forth in section 1732.1(e), may be approved shall, upon satisfactory completion, be considered approved continuing education for pharmacists. for credit for pharmacists. upon written petition to the Board.~~

NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

§1732.3. Coursework Approval for Providers.

(a) Unless denied by the accreditation agency upon audit, all coursework offered by California recognized providers is considered as approved in California.

(b) On a random basis established by the Board or in response to complaints about a particular provider or requests by the Board, the accreditation agency shall review selected coursework. Within 15 days of receipt of written notification, the provider shall submit to the accreditation agency all material deemed necessary by the Committee to review the course. The material shall be forwarded to a reviewer to judge the quality of the program on the basis of factors established by the accreditation agency in addition to those defining relevance to pharmacy practice and educational quality stated in [Section 1732.1\(c\)](#).

(c) A recognized provider's coursework shall be valid for up to three years following the initial presentation provided that the information being presented is still current.

(d) A recognized provider's advertisements for approved coursework shall clearly indicate the provider's name, the coursework's number of hours, date of expiration, the provider number assigned by the accreditation agency and the name of the accrediting agency.

NOTE

Authority cited: Sections 4005, 4206 and 4232, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

§1732.4. Provider Audit Requirements.

Upon written request from the accreditation agency, relating to an audit of coursework, each recognized provider shall submit such materials as are required by the accreditation agency or the Board of Pharmacy.

NOTE

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

§1732.5. Renewal Requirements for Pharmacist

(a) Except as provided in Section 4234 of the Business and Professions Code and [Section 1732.6](#) of this Article, each pharmacist shall submit with the application for renewal proof satisfactory to the Board that,

subsequent to the last renewal thereof, he or she has completed 30 hours of approved continuing education.

(b) All pharmacists shall retain their ~~certificates of completion~~ statements of credit for four (4) years following completion of the program.

NOTE

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

§1732.6. Exemptions

Pharmacists may seek exemption from the continuing education requirements for licensure renewal on the grounds of emergency or hardship by applying to the Board in writing, on a form provided for that purpose, setting forth the reasons why such exemption should be granted. Exemptions may be granted for such reasons as illness or full-time enrollment in a health professional school.

NOTE

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4234, Business and Professions Code

§1732.7. Complaint Mechanism

A provider may request reconsideration of any adverse action taken against the provider or its coursework. Following such reconsideration, the provider may request review of the accreditation agency's decision by the full Board of Pharmacy

NOTE

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code

CA B&P Code 4232.

(a) The courses shall be in the form of postgraduate studies, institutes, seminars, lectures, conferences, workshops, extension studies, correspondence courses, and other similar methods of conveying continuing professional ~~pharmaceutical~~ pharmacy education.

(b) The subject matter shall be pertinent to the socioeconomic and legal aspects of health care, the properties and actions of drugs and dosage forms and the etiology, and characteristics and therapeutics of the disease state.

(c) The subject matter of the courses may include, but shall not be limited to, the following: pharmacology, biochemistry, physiology, pharmaceutical chemistry, pharmacy administration, pharmacy jurisprudence, public health and communicable diseases, professional practice management, anatomy, histology, and any other subject matter as represented in curricula of accredited colleges of pharmacy.

BOARD OF PHARMACY

CALIFORNIA CODE OF REGULATIONS

AMEND TITLE 16, DIVISION 17

AGENDA ITEM C

Memorandum

To: **Licensing Committee**

Date: **June 1, 2004**

From: **Patricia Harris**
 Executive Officer
 Board of Pharmacy

Subject: **Update on the Implementation of NAPLEX/CPJE**

As of May 28, 2004, the board has qualified 1,134 applicants to take the pharmacist licensure examination (the NAPLEX and CPJE). However, as of May 24, 2004, only 284 applicants have taken the CPJE.

The board has processed 1,545 applications out of the 1,673 applications received. There are 128 applications to process with 411 deficient applications pending.

The board anticipates releasing the CPJE scores in approximately two weeks with the goal of issuing pharmacist licenses by mid-June.

Staff has experienced a substantial increase in telephone, faxed and in-person inquiries regarding the examination process. With our limited resources, staff is performing extraordinary to ensure timely processing and licensure of pharmacist applicants.

AGENDA ITEM D

Memorandum

To: Licensing Committee

Date: May 25, 2004

**From: Patricia Harris
 Executive Officer
 Board of Pharmacy**

Subject: Intern Requirements

On April 20, 2004, President John Jones received a letter from the Dean of UCSF, School of Pharmacy, Dr. Mary Anne Koda-Kimble. She wrote the letter on behalf of her fellow California School of Pharmacy Deans. The purpose of the letter was to express concern about the proposed changes to the licensure requirements contained in SB 1913, and to request that the board initiate an open dialogue with them on how the 1,500 hours of pharmacy internship would be defined.

It was explained to Dean Koda-Kimble that SB 1913 is not changing the 1,500 experience requirement that is currently specified in regulation, California Code of Regulations (CCR), title 16, sec. 1728. Specifically SB 1913 is moving the intern requirements from regulation to statute (B&P Code sec. 4030), the length of time and circumstances that an intern pharmacist license may be issued (B&P Code sec. 4208), that the intern pharmacist must complete the 1,500 hours prior to applying for the pharmacist licensure examination and that the experience must comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy education (B&P Code sec. 4209).

In her letter, Dean Koda-Kimble discussed the 1,500-intern requirement that is required by section 1728. Pharmacist interns must complete a minimum of 900 hours in a pharmacy under the supervision of a preceptor. Then the board can grant at its discretion a maximum of 600 hours for other experiences that substantially relates to the practice of pharmacy. California pharmacy students are granted the 600 hours for completing the School's Advanced Pharmacy Practice Experiences (APPEs or clerkships).

There is concern by the schools that SB 1913 changes the 1,500 intern requirement so that California pharmacy students will not be required to complete any intern hours of pharmacy practice experience beyond those associated with their formal curriculum in the School of Pharmacy. The bill does not make this change.

The Licensing Committee initiated review of the intern program last June as part of its strategic objective. The program was discussed at subsequent meetings until December, when the committee recommended to the board that the intern requirements be placed in legislation. The board acted on this recommendation at its January 2004 meeting. It

should be noted that once SB 1913 passes, the board will need to amend CCR 1728, to make it consistent with the new statutory changes.



School of Pharmacy
Office of the Dean

APR 20 2004 11:23

Mary Anne Koda-Kimble, Pharm.D.
Professor and Dean
T.J. Long Chair in
Chain Pharmacy Practice
521 Parnassus Avenue
Box 0622, Room C-156
San Francisco, CA 94143
tel: 415/476-8010
fax: 415/476-6632
email: makx@itsa.ucsf.edu
Internet: <http://pharmacy.ucsf.edu>

April 20, 2004

John Jones, PharmD
President, State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

Dear John:

I write this letter on behalf of my fellow California School of Pharmacy Deans as listed below. We write to express our concern about the proposed changes in the requirements for licensure outlined in SB 1913 and to request that you open a dialogue with us about the proposed changes in how the 1500 hours of pharmacy internship are defined.

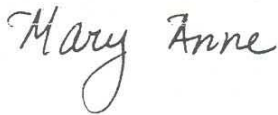
Currently, 1500 hours of internship are required for licensure in California. Of these, 600 hours in experiences that are "substantially related" to the practice of pharmacy can be credited toward the 1500-hour requirement. The Board has taken a broad view of the experiences it will accept as those "substantially related to" the practice of pharmacy, and we support this practice. The remaining 900 hours of internship must take place in a licensed pharmacy under the supervision of a licensed pharmacist performing specifically outlined tasks or activities as outlined in the pharmacist's scope of practice. These hours are fairly narrowly defined, reflecting what the public perceives to be the primary responsibilities of pharmacists in community and hospital pharmacy settings.

The California Schools of Pharmacy have always considered the minimum 900-hour internship experience as a key element in the full development of a practicing pharmacist. Consequently, we have designed our academic curricula in ways that take advantage of and further build on these experiences. Some California schools offer early practice experiences that are consistent with the competencies outlined by the Board. They have appropriately petitioned the board to give students completing these experiences credit toward the "900" hour component. Clearly, while some of the School's Advanced Pharmacy Practice Experiences (APPEs or clerkships) meet the Board's definition of "in a pharmacy under the supervision of a pharmacist," the majority of our APPEs do not.

If SB 1913 is implemented as proposed, students will not be required to complete any intern hours of pharmacy practice experience beyond those associated with their formal curriculum in the School of Pharmacy. As a result, our students would be eligible for licensure having completed approximately half of the currently required professional experience hours. Furthermore, there certainly is no guarantee that they would have the sufficient depth and breadth of experience needed to achieve a beginning level of competency in those areas currently outlined by the board.

We are, therefore, concerned that this situation would not be in the public's best interest and are eager to discuss this with the Board. We look forward to hearing from you.

Best regards,

A handwritten signature in cursive script that reads "Mary Anne".

Mary Anne Koda-Kimble, Pharm.D.
Professor and Dean, School of Pharmacy
University of California at San Francisco

Timothy Chan, Ph.D.
Dean, School of Pharmacy
University of Southern California

Avis Ericcson, Pharm.D.
Interim Dean, School of Pharmacy
Loma Linda University

Phillip Oppenheimer, Pharm.D.
Dean, Thomas J. Long School of Pharmacy & Health Sciences
University of the Pacific

Max D. Ray, Pharm. D.
Dean, College of Pharmacy
Western University of Health Sciences

Palmer Taylor, Ph.D.
Dean, School of Pharmacy and Pharmaceutical Sciences
University of California at San Diego

AMENDED IN SENATE APRIL 21, 2004

SENATE BILL

No. 1913

**Introduced by Committee on Business and Professions (Senators
Figueroa (Chair), Brulte, Cedillo, Machado, Murray, and
Vincent)**

March 17, 2004

An act to amend Sections 28, 1274, 2041, 2462, 2470.14, 2902, 2915.7, 2936, 4005, 4030, 4059.5, 4076, 4081, 4101, 4114, 4200, 4409, 4980.395, 4990.4, ~~4995.26, 4996.18, and 4996.20~~ 4996.18, 4996.20, and 4996.25 of, and to add Sections 4026.5, 4107, 4208, and 4209 to, the Business and Professions Code, and to amend Sections 11159.1, 11207, and 111625 of the Health and Safety Code, relating to professions.

LEGISLATIVE COUNSEL'S DIGEST

SB 1913, as amended, Committee on Business and Professions. Professions.

(1) Existing law provides for the licensing and regulation of psychologists, clinical social workers, and marriage and family therapists. Existing law requires a person applying for licensure as a psychologist, clinical social worker, or marriage and family therapist on and after January 1, 1987, to have completed specified coursework or training in child abuse assessment and reporting from certain types of institutions.

This bill would revise the types of educational institutions from which the training may be obtained.

(2) Existing law provides for the regulation of clinical laboratories. Existing law requires a clinical laboratory to send to persons submitting cytological samples for evaluation information letters on all cases of

1 prepared, furnished, or dispensed; providing for standards of
2 minimum equipment for establishments licensed under this
3 chapter; pertaining to the sale of drugs by or through any
4 mechanical device; and relating to pharmacy practice experience
5 necessary for licensure as a pharmacist.

6 (b) Notwithstanding any provision of this chapter to the
7 contrary, the board may adopt regulations permitting the
8 dispensing of drugs or devices in emergency situations, and
9 permitting dispensing of drugs or devices pursuant to a
10 prescription of a person licensed to prescribe in a state other than
11 California where the person, if licensed in California in the same
12 licensure classification would, under California law, be permitted
13 to prescribe drugs or devices and where the pharmacist has first
14 interviewed the patient to determine the authenticity of the
15 prescription.

16 (c) The board may, by rule or regulation, adopt, amend, or
17 repeal rules of professional conduct appropriate to the
18 establishment and maintenance of a high standard of integrity and
19 dignity in the profession. Every person who holds a license issued
20 by the board shall be governed and controlled by the rules of
21 professional conduct adopted by the board.

22 (d) The adoption, amendment, or repeal by the board of these
23 or any other board rules or regulations shall be in accordance with
24 Chapter 3.5 (commencing with Section 11340) of Part 1 of
25 Division 3 of Title 2 of the Government Code.

26 SEC. 10. Section 4026.5 is added to the Business and
27 Professions Code, to read:

28 4026.5. "Good standing" means a license issued by the board
29 that is unrestricted by disciplinary action taken pursuant to Chapter
30 5 (commencing with Section 11500) of Part 1 of Division 3 of Title
31 2 of the Government Code.

32 SEC. 11. Section 4030 of the Business and Professions Code
33 is amended to read:

34 4030. "Intern pharmacist" means a person issued a license
35 pursuant to Section 4208.

36 SEC. 12. Section 4059.5 of the Business and Professions
37 Code is amended to read:

38 4059.5. (a) Except as otherwise provided in this chapter,
39 dangerous drugs or dangerous devices may only be ordered by an
40 entity licensed by the board and shall be delivered to the licensed

1 employee that violate this section and of which the
2 pharmacist-in-charge or exemptee-in-charge had no knowledge,
3 or in which he or she did not knowingly participate.

4 SEC. 15. Section 4101 of the Business and Professions Code
5 is amended to read:

6 4101. (a) A pharmacist who takes charge of, or acts as
7 pharmacist-in-charge of a pharmacy or other entity licensed by the
8 board, who terminates his or her employment at the pharmacy or
9 other entity, shall notify the board within 30 days of the
10 termination of employment.

11 (b) An exemptee-in-charge of a wholesaler or veterinary food
12 drug-animal retailer, who terminates his or her employment at that
13 entity shall notify the board within 30 days of the termination of
14 employment.

15 SEC. 16. Section 4107 is added to the Business and
16 Professions Code, to read:

17 ~~4107. (a) The board may not issue or, effective July 1, 2005,~~
18 ~~renew a site license, including, but not limited to, a license to~~
19 ~~conduct a wholesaler, pharmacy, veterinary food-animal drug~~
20 ~~retailer, to a facility located in a personal residence.~~

21 ~~(b)~~

22 4107. The board may not issue more than one site license to
23 a single premises except to issue a veterinary food-animal drug
24 retailer license to a wholesaler or to issue a license to compound
25 sterile injectable drugs to a pharmacy. For the purposes of this
26 subdivision, "premises" means a location with its own address
27 and an independent means of ingress and egress.

28 SEC. 17. Section 4114 of the Business and Professions Code
29 is amended to read:

30 4114. (a) An intern pharmacist may perform all functions of
31 a pharmacist at the discretion of and under the supervision of a
32 pharmacist whose license is in good standing with the board.

33 (b) A pharmacist may not supervise more than two intern
34 pharmacists at any one time.

35 SEC. 18. Section 4200 of the Business and Professions Code
36 is amended to read:

37 4200. (a) The board may license as a pharmacist any
38 applicant who meets all the following requirements:

39 (1) Is at least 18 years of age.

1 (2) (A) Has graduated from a college of pharmacy or
2 department of pharmacy of a university recognized by the board;
3 or

4 (B) If the applicant graduated from a foreign pharmacy school,
5 the foreign-educated applicant has been certified by the Foreign
6 Pharmacy Graduate Examination Committee.

7 (3) Has completed at least 150 semester units of collegiate
8 study in the United States, or the equivalent thereof in a foreign
9 country. No less than 90 of those semester units shall have been
10 completed while in resident attendance at a school or college of
11 pharmacy.

12 (4) Has earned at least a baccalaureate degree in a course of
13 study devoted to the practice of pharmacy.

14 (5) Has carried 1,500 hours of pharmacy practice experience or
15 the equivalent in accordance with Section 4209.

16 (6) Has passed a written and practical examination given by the
17 board prior to December 31, 2003, or has passed the North
18 American Pharmacist Licensure Examination and the Multi-State
19 Pharmacy Jurisprudence Examination for California on or after
20 January 1, 2004.

21 (b) Proof of the qualifications of an applicant for licensure as
22 a pharmacist, shall be made to the satisfaction of the board and
23 shall be substantiated by affidavits or other evidence as may be
24 required by the board.

25 (c) Each person, upon application for licensure as a pharmacist
26 under this chapter, shall pay to the executive officer of the board,
27 the fees provided by this chapter. The fees shall be compensation
28 to the board for investigation or examination of the applicant.

29 SEC. 19. Section 4208 is added to the Business and
30 Professions Code, to read:

31 4208. (a) At the discretion of the board, an intern pharmacist
32 license may be issued for a period of:

33 (1) One to six years to a person who is currently enrolled in a
34 school of pharmacy recognized by the board.

35 (2) Two years to a person who is a graduate of a school of
36 pharmacy recognized by the board and who has applied to become
37 licensed as a pharmacist in California.

38 (3) Two years to a foreign graduate who has met educational
39 requirements described in paragraphs (1) to (4), inclusive, of
40 subdivision (a) of Section 4200.

1 (4) One year to a person who has failed the pharmacist
2 licensure examination four times and has reenrolled in a school of
3 pharmacy to satisfy the requirements of Section 4200.1.

4 (b) The board may issue an intern pharmacist license to an
5 individual for the period of time specified in a decision of
6 reinstatement adopted by the board.

7 (c) An intern pharmacist shall notify the board within 30 days
8 of any change of address.

9 (d) An intern pharmacist whose license has been issued
10 pursuant to paragraph (1) or paragraph (4) of subdivision (a) shall
11 return his or her license, by registered mail, within 30 days of no
12 longer being enrolled in a school of pharmacy. The intern
13 pharmacist license will be cancelled by the board.
14 Notwithstanding subdivision (c), an intern pharmacist license may
15 be reinstated if the student re-enrolls in a school of pharmacy
16 recognized by the board to fulfill the education requirements of
17 paragraphs (1) to (4), inclusive, of subdivision (a) of Section 4200.

18 SEC. 20. Section 4209 is added to the Business and
19 Professions Code, to read:

20 4209. (a) An intern pharmacist shall complete 1,500 hours of
21 pharmaceutical experience before applying for the pharmacist
22 licensure examination.

23 (1) This pharmaceutical experience shall comply with the
24 Standards of Curriculum established by the Accreditation Council
25 for Pharmacy Education or with regulations adopted by the board.

26 (b) An intern pharmacist shall submit proof of his or her
27 experience on board-approved affidavits, which shall be certified
28 under penalty of perjury by a pharmacist under whose supervision
29 such experience was obtained or by the pharmacist-in-charge at
30 the pharmacy while the pharmacist intern obtained the experience.

31 (c) An applicant for the examination who has been licensed as
32 a pharmacist in any state for at least one year, as certified by the
33 licensing agency of that state, shall be exempt from subdivision
34 (a). Certification of an applicant's licensure in another state shall
35 be submitted in writing and signed, under oath, by a duly
36 authorized official of the state in which the license is held.

37 SEC. 21. Section 4409 of the Business and Professions Code
38 is amended to read:

39 4409. At the time a pharmacy license is renewed pursuant to
40 subdivision (a) of Section 4110 or a pharmacist license is renewed

AMERICAN COUNCIL ON PHARMACEUTICAL EDUCATION

**ACCREDITATION STANDARDS AND GUIDELINES FOR THE
PROFESSIONAL PROGRAM IN PHARMACY LEADING TO
THE DOCTOR OF PHARMACY DEGREE
ADOPTED JUNE 14, 1997**

**The American Council on Pharmaceutical Education, Inc.
Chicago, Illinois
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Proposed B+P Code section 4209(a)(1)

Standard No. 8. The Curriculum in Pharmacy

The College or School of Pharmacy should offer a curriculum in pharmacy intended to prepare its graduates to become generalist practitioners of pharmacy. The goals and objectives of the curriculum in pharmacy should embrace the scope of contemporary practice responsibilities as well as emerging roles that ensure the rational use of drugs in the individualized care of patients as well as in patient populations. The organized program of study should provide students with a core of knowledge, skills, abilities, attitudes, and values that are necessary to the provision of pharmaceutical care and should provide opportunity for selection by students of courses and professional experiences in keeping with particular interests and goals. The need for life-long learning should be reflected as an integral theme of the curriculum.

Standard No. 9. Curricular Organization and Length

The curriculum in pharmacy should provide sufficient content for the achievement of the professional competencies necessary to the general practice of pharmacy and to satisfy educational requirements for licensure as a pharmacist, and should meet the requirements of the institution for the doctor of pharmacy degree. The College or School of Pharmacy's organized plan of study should focus upon the content, sequence, process, and outcomes of the curriculum. The curriculum for the professional program in pharmacy requires a minimum of four academic years or the equivalent in order to ensure achievement of the professional competencies necessary to become a generalist practitioner who renders pharmaceutical care.

Standard No. 10. Professional Competencies and Outcome Expectations

Professional competencies that should be achieved through the College or School of Pharmacy's curriculum in pharmacy are an ability to:

- a. evaluate drug orders or prescriptions, accurately and safely compound drugs in appropriate dosage forms, and package and dispense dosage forms;
- b. manage systems for storage, preparation, and dispensing of medicines, and supervise technical personnel who may be involved in such processes;
- c. manage and administer a pharmacy and pharmacy practice;
- d. apply computer skills and technological advancements to practice;
- e. communicate with health care professionals and patients regarding rational drug therapy, wellness, and health promotion;
- f. design, implement, monitor, evaluate, and modify or recommend modifications in drug therapy to insure effective, safe, and economical patient care;
- g. identify, assess, and solve medication-related problems, and provide a clinical judgment as to the continuing effectiveness of individualized therapeutic plans and intended therapeutic outcomes;
- h. evaluate patients and order medications and/or laboratory tests in accordance with established standards of practice;
- i. evaluate patient problems and triage patients to other health professionals as appropriate;
- j. administer medications;
- k. monitor and counsel patients regarding the purposes, uses, and effects of their medications and related therapy;
- l. understand relevant diet, nutrition, and non-drug therapies;
- m. recommend, counsel, and monitor patient use of nonprescription drugs;
- n. provide emergency first care;

- o. retrieve, evaluate, and manage professional information and literature;
- p. use clinical data to optimize therapeutic drug regimens;
- q. collaborate with other health professionals; and
- r. evaluate and document interventions and pharmaceutical care outcomes.

Outcome expectations for student performance in the professional competencies stated above should be set forth and measured by the College or School. The process of measuring outcome expectations should include student self-assessments of performance in the stated professional competencies.

Standard No. 11. Areas and Content of Curricular Core

The areas and content of the curriculum in pharmacy should provide the student with a core of knowledge, skills, abilities, attitudes, and values which, in composite, relate to the professional competencies and outcome expectations set forth in Standard No. 10. Professional Competencies and Outcome Expectations. The areas and content of the curriculum in pharmacy should be in phase with one another and should be

balanced in accord with the College or School of Pharmacy's mission, goals, and objectives. The areas and content of the curricular core are as follows:

biomedical sciences, including content in anatomy, physiology, pathophysiology, microbiology, immunology, biochemistry, molecular biology, and biostatistics;
 pharmaceutical sciences, including content in medicinal chemistry, pharmacognosy, pharmacology, toxicology, and pharmaceutics which encompasses physical/chemical principles of dosage forms and drug delivery systems, biopharmaceutics, and pharmacokinetics;
 behavioral, social, and administrative pharmacy sciences, including content in health care economics, pharmacoconomics, practice management, communications applicable to pharmacy, the history of pharmacy, ethical foundations to practice, and social and behavioral applications and laws pertaining to practice;
 pharmacy practice, including content in prescription processing, compounding and preparation of dosage forms, including parenteral products, drug distribution and drug administration, epidemiology, pediatrics, geriatrics, gerontology, nutrition, health promotion and disease prevention, physical assessment, emergency first-care, clinical laboratory medicine, clinical pharmacokinetics, patient evaluation and ordering medications, pharmacotherapeutics, disease-state management, outcomes documentation, self care/non-prescription drugs, and drug information and literature evaluation; and
 professional experience, including introductory and advanced practice experiences acquired throughout the curriculum as a continuum, progressing from the Introductory Pharmacy Practice Experiences through the Advanced Pharmacy Practice Experiences in a variety of practice settings.

Guideline 11.1

Instruction in the use of new and innovative technologies in the provision of pharmaceutical care, such as information systems and biotechnology, should be integrated throughout the areas and content of the core curriculum.

Guideline 11.2

The biomedical and pharmaceutical sciences should be of such depth, scope, timeliness, quality, sequence, and emphasis to provide the foundation for and support of the intellectual and clinical objectives of the professional program in pharmacy. The biomedical sciences should provide the basis for understanding and treating humans in health and disease. Where instruction is provided in the biomedical sciences by other academic units of the University, these areas should be developed in accord with the goals and objectives for the curriculum in pharmacy. Appropriate liaison mechanisms should be established to insure effective instructional delivery and to assure satisfaction of biomedical science objectives for the professional program in pharmacy.

Guideline 11.3

The behavioral, social, and administrative pharmacy sciences should provide the basis for understanding and influencing human behavior in health and disease, in the management process of pharmacy, and in pharmacy's interrelationships with health care systems. The behavioral, social, and administrative pharmacy sciences should attend to the knowledge, skills, abilities, attitudes, and values necessary to the efficient and effective management of patient-centered practice, including administrative and management matters related to

drugs and supplies, as well as administrative and management activities related to personnel and finances. Moreover, the behavioral, social, and administrative pharmacy sciences area should contribute to the development and implementation of care plans and to the management of the patient's drug therapies.

Guideline 11.4

The professional experience should be of adequate intensity, breadth, and duration so as to support achievement of stated competencies as demonstrated by assessment of outcome expectations. Students should be duly enrolled in the College or School of Pharmacy and should not receive monetary remuneration for professional experience so as to assure the primacy of an appropriate student/teacher relationship.

Guideline 11.5

The Introductory Pharmacy Practice Experiences should be offered in various practice settings during the early sequencing of the curriculum for purposes of providing transitional experiential activities and active learning. Such practice experiences should be organized as a curricular progression leading to advanced practice experiences so as to support growth in the student's capabilities to render pharmaceutical care. The scope and breadth of the introductory experiences should involve the initial development of practice skills, and should be consistent with these stated purposes. A quality control procedure should be established in accord with stated purposes and outcome expectations; the Introductory Pharmacy Practice Experiences may be designed in conjunction with didactic courses or as a discrete experiential offering.

Guideline 11.6

The Advanced Pharmacy Practice Experiences should provide active participation and in-depth experiences to acquire practice skills and judgment and to develop, in a graded fashion, the level of confidence and responsibility needed for independent and collaborative practice. Toward this end, a spectrum of practice experiences should be deployed wherein the biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and pharmacy practice are integrated, professional knowledge and skills are applied, and professional attitudes, ethics, and behaviors are developed so as to enable students to provide pharmaceutical care. Advanced practice experiences should enhance communication and collaborative skills with patients and other professionals, including the ability to work and communicate effectively with diverse colleagues and patients. The advanced practice experiences should also provide experience in prescription processing, compounding and preparation of dosage forms, including parenteral products, drug distribution systems, documentation of services, the taking of drug histories, participating in drug therapy decisions, monitoring, educating, and counseling patients, solving problems, and systematically evaluating drug use. Advanced practice experiences should include application of clinical pharmacokinetic principles in the development and management of dosing and should incorporate knowledge and skills in the searching, analysis, and interpretation of drug information. Students should be under the close supervision of pharmacist role models.

Guideline 11.7

The organization of the Advanced Pharmacy Practice Experiences should provide a balanced series of core and selective experiences that cumulatively provide sustained experiences of adequate intensity, breadth, and duration to enable achievement of stated competencies as demonstrated by assessment of outcome expectations. Generally, the core and selective experiences should be full-time and provide continuity of care, with pharmacy faculty supervision and monitoring. The duration of the Advanced Pharmacy Practice Experiences should ordinarily be the equivalent of one academic year. Core experiences should develop pharmaceutical care capabilities in inpatient and ambulatory care settings, especially community pharmacies. Selective experiences should complement the core experiences and provide adequate and innovative opportunities for students to mature professionally in accord with their individualized interests. The series of core and selective experiences should be philosophically and educationally coordinated to achieve, in composite, the experiential whole of the Advanced Pharmacy Practice Experiences.

Guideline 11.8

The Advanced Pharmacy Practice Experiences should be provided in both ambulatory and inpatient settings and should include primary, acute, chronic, and preventive care among patients of all ages. The core experiences should provide substantial experience in community pharmacy practice and hospital/institutional pharmacy practice, as well as substantial practice experience with general medicine acute care patients. Most of the advanced practice experiences should involve direct patient care. However, some of the advanced practice experiences may involve indirect patient care or may occur in non-patient care areas, such as research and management. Other experiences, such as those in drug information, managed care, and home health care should be available.

Guideline 11:2

A quality control procedure for the Advanced Pharmacy Practice Experiences should be established for core and selective experiences so as to facilitate achievement of stated competencies, provide for feedback, assure reasonable standardization, and insure consistency in evaluation. The College or School should assure that all practice facilities utilized for the advanced practice experiences meet and sustain conditions necessary to the delivery of pharmaceutical care and to the students' learning needs through the establishment of a mechanism such as the use of a review council. This review council, or other established mechanism *for* quality control, should involve individuals with appropriate expertise and perspectives, such as student, practitioner, and board of pharmacy representation. The core and selective experiences should be organized, administered, and evaluated in accord with their individualized goals and objectives and in keeping with the overall goals and objectives for the advanced practice experiences. General objectives and learning modules as well as site specific guidelines should be established for the core and selective experiences. Specific criteria should be developed so as to enable faculty and students to assess both formative and summative progress. Students should be provided the opportunity to demonstrate achievement of stated competencies as evaluated through the use of reliable, validated criteria.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200.1, Business and Professions Code.

§1726. Preceptor.

- (a) A preceptor is a pharmacist registered in any state whose license is not revoked, suspended or on probation in any state in which he or she is now or has been registered.
- (b) The preceptor shall supervise the intern's activities to provide the experience necessary to make the intern proficient in the provision of pharmaceutical services.
- (c) The preceptor shall be responsible for all professional activities performed by the intern under his or her supervision.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4114 and 4200, Business and Professions Code.

§1727. Intern Pharmacist.

- (a) An intern pharmacist is a person who holds a valid intern card.
- (b) An intern card shall be issued for a period of:
 - (1) One to five years for the person who is currently enrolled in a school of pharmacy recognized by the Board.
 - (2) One year to a person who is a graduate of a school of pharmacy recognized by the Board.
 - (3) One year to a foreign graduate who has met educational requirements described in Business and Professions Code Section 4200.
 - (4) One year to an out-of-state licentiate who is awaiting the administration of the next licensure examination.
- (c) Registration as an intern may be renewed or extended at the sole discretion of the Board for:
 - (1) Persons who have not completed experience requirements.
 - (2) Persons who have completed experience requirements but have not taken or passed the licensure examination.Intern cards shall not be extended or renewed for a person who failed the licensure examination three or more times.
- (d) An intern shall notify the Board within 30 days of any change of address. An intern shall return his or her intern card, by registered mail, within thirty (30) days of a change of eligibility status.
- (e) An intern pharmacist may perform all functions of a pharmacist at the discretion and under the supervision of a preceptor in accordance with Business and Professions Code Section 4114.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4114 and 4200, Business and Professions Code.

§1728. Intern Experience--Requirements for Licensure.

- (a) Minimum Hours: All intern pharmacists must complete 1,500 hours of experience as a prerequisite to licensure.
 - (1) First Year Maximum: A maximum of 250 of the 1,500 hours may be obtained during the first year of pharmacy education in a program sponsored by a school of pharmacy recognized by the Board.
 - (2) Preceptor Supervision: A minimum of 900 of the required 1,500 hours must be obtained in a pharmacy under the supervision of a preceptor.
 - (3) Board Approved Experience: A maximum of 600 of the required 1,500 hours may be granted at the discretion of the Board for other experience which substantially relates to the practice of pharmacy.
- (b) Required Areas of Experience: Effective January 1, 1986 all applicants for licensure must complete experience in both community pharmacy and institutional pharmacy practice in settings in the following areas:
 - (1) Receiving and interpreting the prescription;
 - (2) Patient medication profiles;
 - (3) Prescription preparation;
 - (4) Consultation;
 - (5) Record keeping;
 - (6) Over the counter products;
 - (7) Drug information.
- (c) Proof of Experience: All intern pharmacists are required to submit proof of their experience on Board approved affidavits which shall be certified by the preceptor under whose immediate supervision such experience was obtained.
- (d) Out-of-State Exemption: One who is licensed as a pharmacist in any state and who has practiced as a pharmacist in that state for at least one year, as certified by the Board of Pharmacy of that state, shall be exempt from the pharmaceutical requirements of this section.

AGENDA ITEM E



California State Board of Pharmacy

400 R Street, Suite 4070, Sacramento, CA 95814
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

June 2, 2004

To: Licensing Committee

From: Dennis Ming, Supervising Inspector

RE: Sterile Compounding License Renewal Process – Status Report

Since the inception of the Sterile Compounding Licensing program in July, 2003, the Board of Pharmacy has received and processed **238** applications and has approved **184** Sterile Compounding licenses, of which **16** are out of state, for an average of **77%**.

The top three reasons for delays in approving applications when received are:

1. Lack of adequate/detailed policies and procedures required for compliance with California Code of Regulations 1751.
2. Incomplete applications relative to corporate officers, owners, etc. (amendments required)
3. Pharmacy permit pending (non resident and resident)

Inspections for new applications are completed within 3 weeks of assignment to a Compliance Team inspector.

As required by Business and Professions Code, Section 4127.1, subdivision (C), *“A license to compound injectable sterile drug products may not be renewed until the location has been inspected by the board and found to in compliance with this article and regulations adopted by the board”.*

Starting in April, 2004, the board began re-inspections of pharmacies previously issued a Sterile Compounding License. To date **31** pharmacies issued Sterile Compounding licenses in 2003 were re-inspected. None were found to be out of compliance and none were denied renewal of their sterile compounding license. All were found to be in compliance for purposes of renewal.

To maintain continuity in the licensing and inspection process, the re-inspections were assigned to inspectors who conducted the initial licensing inspection. A separate checklist was created to assist the inspector in comparing results of the initial licensing inspection to the observations made during the re-inspection (attachment I). The results of the re-inspection as well as the status of the pharmacy during the initial licensing inspection were discussed with each

licensee/owner. This process enabled the inspector to identify areas of on-going compliance as well as trends/patterns in non-compliance with California Code of Regulations, Section 1751.

Once completed, the inspectors faxed copies of the completed inspection report as well as the checklist to the Supervising Inspector for review.

Initial results of the re-inspection process are as follows (per CCR 1751):

CCR 1751: Compounding Area for Parenteral Solutions: All of the pharmacies maintained on an on-going basis, the environment for the compounding sterile injectable drugs in compliance with this section.

CCR 1751.1 Laminar Flow Biological Safety Cabinet: One or two of the pharmacies converted from standard class 100 laminar air flow cabinets to class 100 barrier isolators in anticipation of the implementation of revised California Code of Regulations Section 1751 which requires specific environments in which to compound sterile injectable drugs from a non-sterile source. Pharmacies maintained annual certification of the laminar airflow hoods.

CCR 1751.2: Labeling Requirements: Pharmacies maintained compliance with this regulation. Pharmacies who contract with another pharmacy to compound sterile injectable drugs (Business and Professions Code Section 4123) were required to have the label of the compounding and dispensing pharmacy on the container.

CCR 1751.3: Record Keeping: Record keeping as required under current regulation will be changed when the revision to 1751(R) are finally approved and implemented. An area where record keeping was not strictly adhered to was radiopharmacies whose products are primarily intended for one time use and often for diagnostic purposes. In these cases, strict adherence to the record keeping requirements was not always possible or practical. Revisions to CCR 1751 will address and resolve these issues regarding record keeping requirements.

CCR 1751.4: Protective Clothing: This section was intended for pharmacies preparing cytotoxic (chemotherapeutic) medications for injection and for those pharmacies, compliance was on going.

CCR 1751.5: Training of Staff, Patient and Caregiver: Since the inception of the sterile compounding regulations, pharmacies were made more aware of the requirement to train and document competencies of the staff relative to utilizing aseptic technique etc. in the preparation of sterile injectable drugs. Records are being maintained; however, this area should be carefully monitored during the re-inspection process to ensure complete compliance.

CCR 1751.6: Disposal of Waste Material: Pharmacies were observed disposing of waste material from the preparation of sterile injectable drugs in an appropriate manner. Pharmacies compounding chemotherapeutic drugs disposed of residue in the appropriate chemo containers.

CCR 1751.7: Quality Assurance: This section has been the most problematic for pharmacies to maintain compliance. Results of the re-inspection demonstrate that a few pharmacies neglected

to maintain records of cleaning, calibration of equipment, process validation, and end product testing. Some were confused as to how many tests should be done and how often. It would be beneficial to provide feed-back to licensees either in future issues of the SCRIPT or on the Board of Pharmacy web site on how to maintain compliance with quality assurance in pharmacies compounding sterile injectable drugs. None of the pharmacies that were observed to be weak in compliance with this section were issued written warnings of non-compliance; rather they were instructed by the inspector in how to improve their compliance.

CCR 1751.8: Policies and Procedures: Pharmacies maintained their written policies and procedures and a few have submitted revisions for review upon receiving the renewal notice from the board.

CCR 1751.9: Reference Materials: Pharmacies have maintained compliance with this section in having the necessary resource information for compounding sterile injectable drugs.

Future Plans and Action:

1. Continue to conduct new and re-inspections for pharmacies applying for a sterile compounding license.
2. Provide additional information to the Executive Officer regarding the impact on inspector workload in conducting annual re-inspections of pharmacies compounding sterile injectable drugs relative to areas of compliance and non-compliance.
3. Continue to provide consultative/educational services to licensees to achieve and/or maintain compliance with sterile compounding regulations.
4. Modify the current sterile compounding checklist on the board web site to reflect the revisions in CCR 1751 (when approved for implementation).

AGENDA ITEM F

Memorandum

To: **Licensing Committee**

Date: **May 25, 2004**

From: **Patricia Harris**
 Executive Officer
 Board of Pharmacy

Subject: **EC Protocol**

SB 490 (Chapter 651, Statutes of 2003) permits pharmacists to furnish emergency contraception medications based on a statewide protocol adopted by the California State Board of Pharmacy and the Medical Board of California.

The protocol is available on the board's Web site and has been provided to the pharmacists associations for distribution. However, in order for the board to enforce the protocol, it must be adopted as a regulation. The proposed regulation has been noticed for adoption at the July board meeting.

Pharmacists Protocol for Dispensing Emergency Contraception

Senate Bill 490 (Chapter 651, Statutes of 2003) permits pharmacists to furnish emergency contraception medications based on a statewide protocol adopted by the California State Board of Pharmacy and the Medical Board of California.

On the following page is the approved protocol. Pharmacists may use this protocol after they have completed one hour of continuing education credit in emergency contraception (a requirement of the new law).

Prior legislation (Senate Bill 1169, Chapter 900, Statutes of 2001) permits pharmacists to furnish emergency contraception medications to patients based on a protocol with a single licensed prescriber. Existing protocols developed with a prescriber remain valid.

The protocol was prepared with the intent to keep it simple and to comply with the statutory requirements established by Senate Bill 490.

The statutory provisions for pharmacists furnishing emergency contraception are found in California Business and Professions Code section 4052.

Protocol for Pharmacists Furnishing Emergency Contraception (EC)

Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the Board of Pharmacy and the Medical Board of California. Use of the following protocol satisfies that requirement.

Purpose: To provide access to emergency contraceptive medication within required limits and ensure that the patient receives adequate information to successfully complete therapy.

Procedure: When a patient requests emergency contraception the pharmacist will ask and state the following:

- Are you allergic to any medications?
- Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) of unprotected intercourse. EC effectiveness declines gradually over five days and EC use will not interfere with an established pregnancy.

The pharmacist shall provide the fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medical record by Section 1707.1 of Title 16 of the California Code of Regulations (reference attached).

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy.

Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

Advanced Provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

EC Product Selection: The pharmacist will provide emergency contraception medication compatible with product information from the list of products appended to this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC. Patients will be provided information concerning dosing and potential adverse effects.

Documentation: Each prescription authorized by a pharmacist will be documented in a patient profile as required by law.

Training: Prior to furnishing emergency contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

Appendix 1 -- Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.

Brands and Doses Of Oral Contraceptive Tablets Used For Emergency Contraception

<i>Dedicated Emergency Contraception</i>				
Brand	Manufacturer	Tablets per Dose	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
One Dose Regimen				
Plan B	Women's Capital Corporation	2 tablets	0	1.5
Two Dose Regimens				
Plan B	Women's Capital Corporation	1 tablet per dose	0	0.75
Preven	Gynetics	2 tablets per dose	100	0.50
<i>Oral Contraceptive Pills</i>				
Brand	Manufacturer	Tablets per Dose (two doses 12 hours apart *)	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)*
Levora	Watson	4 white tablets	120	0.60
Ovral	Wyeth	2 white tablets	100	0.50
Ogestrel	Watson	2 white tablets	100	0.50
Nordette	Wyeth	4 light-orange tablets	120	0.60
Tri-Levlen	Berlex	4 yellow tablets	100	0.50
Alesse	Wyeth	5 pink tablets	100	0.50
Aviane	Duramed	5 orange tablets	100	0.50
Triphasil	Wyeth	4 yellow tablets	120	0.50
Levlen	Berlex	4 light-orange tablets	120	0.60
Trivora	Watson	4 pink tablets	120	0.50
Levlite	Berlex	5 pink tablets	100	0.50
Lo/Ovral	Wyeth	4 white tablets	120	0.60

Low-Ogestrel	Watson	4 white tablets	120	0.60
Ovrette	Wyeth	20 yellow tablets	0	0.75

* The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel

Appendix 2 -- Sample list of Anti-Emetics for Use with Emergency Contraception.

**Anti-nausea Treatment Options
for use with Emergency Contraception**

Drug	Dose	Timing of Administration
<i>Non-prescription Drugs</i>		
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first ECP dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

TITLE 16. Board of Pharmacy

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on July 12, 2004.

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office not later than 5 p.m. on June 28, 2004.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Section 4005 of the Business and Professions Code and to implement, interpret or make specific Section 4052 of the Business and Professions Code the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Section 4005 of the Business and Professions Code grants the Board of Pharmacy authority to adopt regulations relating to the practice of pharmacy.

Section 4052 of the Business and Professions Code permits a pharmacist to furnish emergency contraception pursuant to a statewide protocol approved by the Board of Pharmacy and the Medical Board of California.

This notice proposed to add Section 1746 as follows:

1. Require a pharmacist dispensing emergency contraception based on the authority granted by Section 4052(a)(8)(ii) to comply with the protocol specified in this section.
2. Establishes the statewide protocol for furnishing emergency contraception. This protocol specifies the procedures to be followed and products to be furnished to patients requesting emergency contraception.

The Board of Pharmacy has proposed to this section to implement a statewide protocol as specified by Senate Bill 490 (Chapter 651, Statutes of 2003).

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None

Business Impact:

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Impact on Jobs/New Businesses:

The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business:

The Board of Pharmacy is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

The Board of Pharmacy has determined that the proposed regulations would not adversely affect small businesses. The Board of Pharmacy made this determination because the proposed regulation would provide pharmacies with greater flexibility in providing emergency contraception products to consumers.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained at the hearing or prior to the hearing upon request from the Board of Pharmacy at 400 R Street, Suite 4070, Sacramento, California 95814, or from the Board of Pharmacy website (www.pharmacy.ca.gov).

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Paul Riches
Address:	400 R Street, Suite 4070 Sacramento, CA 95814
Telephone No.:	(916) 445-5014 x 4016
Fax No.:	(916) 327-6308
E-Mail Address:	Paul_Riches@dca.ca.gov

The backup contact person is:

Name:	Virginia Herold
Address:	400 R Street, Suite 4070 Sacramento, CA 95814
Telephone No.:	(916) 445-5014 x4005
Fax No.:	(916) 327-6308
E-Mail Address:	Virginia_Herold@dca.ca.gov

Website Access: Materials regarding this proposal can be found at www.pharmacy.ca.gov.

**Board of Pharmacy
Emergency Contraception
Add Section 1746**

§1746. Emergency Contraception.

(a) A pharmacist furnishing emergency contraception pursuant to Section 4052 (a)(8)(ii) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).

Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the Board of Pharmacy and the Medical Board of California. Use of the following protocol satisfies that requirement.

Purpose: To provide access to emergency contraceptive medication within required limits and ensure that the patient receives adequate information to successfully complete therapy.

Procedure: When a patient requests emergency contraception the pharmacist will ask and state the following:

- Are you allergic to any medications?
- Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) of unprotected intercourse. EC effectiveness declines gradually over five days and EC use will not interfere with an established pregnancy.

The pharmacist shall provide the fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medical record by Section 1707.1 of Title 16 of the California Code of Regulations (reference attached).

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy.

Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

EC Product Selection: The pharmacist will provide emergency contraception medication compatible with product information from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive

medications indicated for nausea and vomiting associated with taking EC. Patients will be provided information concerning dosing and potential adverse effects.

Documentation: Each prescription authorized by a pharmacist will be documented in a patient profile as required by law.

Training: Prior to furnishing emergency contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.

<u>Dedicated Emergency Contraception</u>				
<u>Brand</u>	<u>Manufacturer</u>	<u>Tablets per Dose</u>	<u>Ethinyl Estradiol per Dose (mg)</u>	<u>Levonorgestrel per Dose (mg)**</u>
<u>One Dose Regimen</u>				
<u>Plan B</u>	<u>Women's Capital Corporation</u>	<u>2 tablets</u>	<u>0</u>	<u>1.5</u>
<u>Two Dose Regimens</u>				
<u>Plan B</u>	<u>Women's Capital Corporation</u>	<u>1 tablet per dose</u>	<u>0</u>	<u>0.75</u>
<u>Preven</u>	<u>Gynetics</u>	<u>2 tablets per dose</u>	<u>100</u>	<u>0.50</u>
<u>Oral Contraceptive Pills</u>				
<u>Brand</u>	<u>Manufacturer</u>	<u>Tablets per Dose (two doses 12 hours apart *)</u>	<u>Ethinyl Estradiol per Dose (mg)</u>	<u>Levonorgestrel per Dose (mg)*</u>
<u>Levora</u>	<u>Watson</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.60</u>
<u>Ovral</u>	<u>Wyeth</u>	<u>2 white tablets</u>	<u>100</u>	<u>0.50</u>
<u>Ogestrel</u>	<u>Watson</u>	<u>2 white tablets</u>	<u>100</u>	<u>0.50</u>
<u>Nordette</u>	<u>Wyeth</u>	<u>4 light-orange tablets</u>	<u>120</u>	<u>0.60</u>
<u>Tri-Levlen</u>	<u>Berlex</u>	<u>4 yellow tablets</u>	<u>100</u>	<u>0.50</u>
<u>Alesse</u>	<u>Wyeth</u>	<u>5 pink tablets</u>	<u>100</u>	<u>0.50</u>
<u>Aviane</u>	<u>Duramed</u>	<u>5 orange tablets</u>	<u>100</u>	<u>0.50</u>
<u>Triphasil</u>	<u>Wyeth</u>	<u>4 yellow tablets</u>	<u>120</u>	<u>0.50</u>
<u>Levlen</u>	<u>Berlex</u>	<u>4 light-orange tablets</u>	<u>120</u>	<u>0.60</u>

<u>Trivora</u>	<u>Watson</u>	<u>4 pink tablets</u>	<u>120</u>	<u>0.50</u>
<u>Levlite</u>	<u>Berlex</u>	<u>5 pink tablets</u>	<u>100</u>	<u>0.50</u>
<u>Lo/Ovral</u>	<u>Wyeth</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.60</u>
<u>Low-Ogestrel</u>	<u>Watson</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.60</u>
<u>Ovrette</u>	<u>Wyeth</u>	<u>20 yellow tablets</u>	<u>0</u>	<u>0.75</u>

Anti-nausea Treatment Options for use with Emergency Contraception

<u>Drug</u>	<u>Dose</u>	<u>Timing of Administration</u>
<u>Non-prescription Drugs</u>		
<u>Meclizine hydrochloride (Dramamine II, Bonine)</u>	<u>One or two 25 mg tablets</u>	<u>1 hour before first EC dose; repeat if needed in 24 hours</u>
<u>Diphenhydramine hydrochloride (Benadryl)</u>	<u>One or two 25 mg tablets or capsules.</u>	<u>1 hour before first EC dose; repeat as needed every 4-6 hours</u>
<u>Dimenhydrinate (Dramamine)</u>	<u>One or two 50 mg tablets or 4-8 teaspoons liquid</u>	<u>30 minutes to 1 hour before first ECP dose; repeat as needed every 4-6 hours</u>
<u>Cyclizine hydrochloride (Marezine)</u>	<u>One 50 mg tablet</u>	<u>30 minutes before first EC dose; repeat as needed every 4-6 hours</u>

NOTE:

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4052, Business and Professions Code.

AGENDA ITEM G

Memorandum

To: Licensing Committee

Date: May 25, 2004

From: Patricia Harris
 Executive Officer
 Board of Pharmacy

Subject: California Pharmacy Manpower Statistics

Attached for your information are some pharmacy manpower statistics for California. The data is displayed by license type, date and county.

As of December 2003, 5,624 pharmacies were licensed with the board. This is a 6.3% increase from January 2001.

As of December 2003, the board 37,756 pharmacy technicians were registered. This is a 41% increase from December 2001, where there were 26,706 registered pharmacy technicians. Also, provided is the number of pharmacy technicians per pharmacists and per pharmacy.

In 2003, there were 24,256 licensed pharmacists with California addresses. This is a 16% increase from 2001, where 20,905 pharmacists were licensed. Also provided is the number of pharmacists per 100,000 Californians.

Pharmacy License Statistics

Board of Pharmacy Data -- December 2003

County	PHY January 2001	PHY December 2003	% Change	Population 1/1/2001 (DOF Est.)	Population 1/1/2004 (DOF Est.)	% Change	Pop. Per PHY 1/1/2001	Pop. Per PHY 12/1/2003	% Change	Average Sq. Miles per PHY 1/1/2001	Average Sq. Miles per PHY 12/1/2003	% Change
Alameda	206	212	2.9%	1,454,302	1,498,000	3.0%	7,272	7,066	-2.8%	4.0	3.9	-2.8%
Alpine	0	0	0.0%	1,193	1,280	7.3%	0	0	0.0%	-	-	-
Amador	7	7	0.0%	34,400	36,850	7.1%	5,264	5,264	0.0%	86.3	86.3	0.0%
Butte	38	41	7.9%	204,046	212,700	4.2%	5,597	5,188	-7.3%	44.1	40.9	-7.3%
Calaveras	5	6	20.0%	38,476	43,350	12.7%	8,670	7,225	-16.7%	207.4	172.8	-16.7%
Colusa	3	3	0.0%	18,755	20,100	7.2%	6,700	6,700	0.0%	385.4	385.4	0.0%
Contra Costa	142	153	7.7%	930,025	1,003,900	7.9%	7,070	6,561	-7.2%	5.6	5.2	-7.2%
Del Norte	5	5	0.0%	28,022	28,250	0.8%	5,650	5,650	0.0%	246.0	246.0	0.0%
El Dorado	20	22	10.0%	152,942	168,100	9.9%	8,405	7,641	-9.1%	89.6	81.4	-9.1%
Fresno	138	151	9.4%	805,005	862,600	7.2%	6,251	5,713	-8.6%	43.6	39.9	-8.6%
Glenn	4	4	0.0%	27,107	27,750	2.4%	6,938	6,938	0.0%	331.8	331.8	0.0%
Humboldt	24	29	20.8%	127,633	130,000	1.9%	5,417	4,483	-17.2%	168.9	139.7	-17.2%
Imperial	18	21	16.7%	145,285	156,600	7.8%	8,700	7,457	-14.3%	249.0	213.4	-14.3%
Inyo	4	4	0.0%	18,193	18,500	1.7%	4,625	4,625	0.0%	2,556.9	2,556.9	0.0%
Kern	101	115	13.9%	658,935	724,900	10.0%	7,177	6,303	-12.2%	80.8	71.0	-12.2%
Kings	14	15	7.1%	131,218	141,400	7.8%	10,100	9,427	-6.7%	99.4	92.8	-6.7%
Lake	11	11	0.0%	55,691	63,200	13.5%	5,745	5,745	0.0%	120.9	120.9	0.0%
Lassen	4	4	0.0%	33,960	34,850	2.6%	8,713	8,713	0.0%	1,180.2	1,180.2	0.0%
Los Angeles	1605	1669	4.0%	9,884,255	10,103,000	2.2%	6,295	6,053	-3.8%	3.0	2.8	-3.8%
Madera	20	19	-5.0%	117,074	135,300	15.6%	6,765	7,121	5.3%	107.7	113.3	5.3%
Marin	34	34	0.0%	249,671	250,200	0.2%	7,359	7,359	0.0%	24.4	24.4	0.0%
Mariposa	2	2	0.0%	16,143	17,650	9.3%	8,825	8,825	0.0%	731.5	731.5	0.0%
Mendocino	19	19	0.0%	87,591	89,200	1.8%	4,695	4,695	0.0%	204.1	204.1	0.0%
Merced	27	28	3.7%	210,138	232,100	10.5%	8,596	8,289	-3.6%	73.0	70.4	-3.6%
Modoc	2	1	-50.0%	9,794	9,650	-1.5%	4,825	9,650	100.0%	2,101.8	4,203.6	100.0%
Mono	2	2	0.0%	10,914	13,500	23.7%	6,750	6,750	0.0%	1,566.0	1,566.0	0.0%
Monterey	49	50	2.0%	399,304	421,400	5.5%	8,600	8,428	-2.0%	77.0	75.4	-2.0%
Napa	16	18	12.5%	127,005	131,600	3.6%	8,225	7,311	-11.1%	49.3	43.8	-11.1%
Nevada	14	14	0.0%	91,097	96,100	5.5%	6,864	6,864	0.0%	69.6	69.6	0.0%
Orange	528	531	0.6%	2,828,351	3,017,300	6.7%	5,715	5,682	-0.6%	1.8	1.8	-0.6%
Placer	51	66	29.4%	234,371	292,100	24.6%	5,727	4,426	-22.7%	29.4	22.7	-22.7%
Plumas	5	5	0.0%	20,341	21,100	3.7%	4,220	4,220	0.0%	522.7	522.7	0.0%
Riverside	217	251	15.7%	1,522,855	1,776,700	16.7%	8,188	7,078	-13.5%	33.7	29.1	-13.5%
Sacramento	181	202	11.6%	1,209,472	1,335,400	10.4%	7,378	6,611	-10.4%	5.5	4.9	-10.4%
San Benito	6	5	-16.7%	49,791	57,100	14.7%	9,517	11,420	20.0%	231.8	278.2	20.0%

San Bernardino	222	248	11.7%	1,689,281	1,886,500	11.7%	8,498	7,607	-10.5%	90.6	81.1	-10.5%
San Diego	388	428	10.3%	2,911,468	3,017,200	3.6%	7,776	7,050	-9.3%	11.7	10.6	-9.3%
San Francisco	142	142	0.0%	801,377	792,700	-1.1%	5,582	5,582	0.0%	1.6	1.6	0.0%
San Joaquin	94	99	5.3%	566,628	630,600	11.3%	6,709	6,370	-5.1%	15.2	14.4	-5.1%
San Luis Obispo	49	52	6.1%	245,191	258,200	5.3%	5,269	4,965	-5.8%	73.8	69.5	-5.8%
San Mateo	88	86	-2.3%	730,029	712,400	-2.4%	8,095	8,284	2.3%	8.4	8.6	2.3%
Santa Barbara	62	70	12.9%	414,155	414,800	0.2%	6,690	5,926	-11.4%	61.1	54.1	-11.4%
Santa Clara	230	244	6.1%	1,736,722	1,731,400	-0.3%	7,528	7,096	-5.7%	5.7	5.3	-5.7%
Santa Cruz	37	39	5.4%	255,021	260,200	2.0%	7,032	6,672	-5.1%	16.4	15.6	-5.1%
Shasta	37	40	8.1%	166,960	175,700	5.2%	4,749	4,393	-7.5%	104.0	96.2	-7.5%
Sierra	1	1	0.0%	3,143	3,520	12.0%	3,520	3,520	0.0%	962.0	962.0	0.0%
Siskiyou	9	10	11.1%	44,184	44,850	1.5%	4,983	4,485	-10.0%	705.3	634.8	-10.0%
Solano	44	46	4.5%	399,026	416,500	4.4%	9,466	9,054	-4.3%	20.6	19.7	-4.3%
Sonoma	65	68	4.6%	450,057	472,700	5.0%	7,272	6,951	-4.4%	27.2	26.0	-4.4%
Stanislaus	70	75	7.1%	441,364	491,900	11.4%	7,027	6,559	-6.7%	21.6	20.2	-6.7%
Sutter	8	13	62.5%	77,878	85,500	9.8%	10,688	6,577	-38.5%	76.1	46.8	-38.5%
Tehama	9	10	11.1%	56,159	58,700	4.5%	6,522	5,870	-10.0%	329.1	296.2	-10.0%
Trinity	3	4	33.3%	13,039	13,450	3.2%	4,483	3,363	-25.0%	1,069.3	802.0	-25.0%
Tulare	50	55	10.0%	367,961	396,800	7.8%	7,936	7,215	-9.1%	96.8	88.0	-9.1%
Tuolumne	10	10	0.0%	52,953	56,900	7.5%	5,690	5,690	0.0%	227.5	227.5	0.0%
Ventura	125	133	6.4%	756,501	802,400	6.1%	6,419	6,033	-6.0%	17.7	16.6	-6.0%
Yolo	18	23	27.8%	162,928	184,500	13.2%	10,250	8,022	-21.7%	56.8	44.5	-21.7%
Yuba	7	9	28.6%	60,711	64,800	6.7%	9,257	7,200	-22.2%	91.9	71.5	-22.2%
Statewide	5290	5624	6.3%	34,336,091	36,143,950	5.3%	6,833	6,427	-5.9%	30.9	29.1	-5.9%

Pharmacy Technician Statistics

Board of Pharmacy Data - December 2003

County	# of Technicians 1/1/2001	# of Technicians 12/1/2003	% Change	Technicians			Technicians		
				per Pharmacist 1/1/2001	per Pharmacist 12/1/2003	% Change	per Pharmacist 1/1/2001	per Pharmacist 12/1/2003	% Change
Alameda	1149	1603	39.5%	1.3	1.5	17.7%	5.6	7.6	35.6%
Alpine	0	0	0.0%	0.0	0.0	0.0%	0.0	0.0	0.0%
Amador	37	45	21.6%	1.8	1.8	2.2%	5.3	6.4	21.6%
Butte	189	254	34.4%	1.4	1.8	24.9%	5.0	6.2	24.6%
Calaveras	31	44	41.9%	2.2	1.9	-13.6%	6.2	7.3	18.3%
Colusa	9	10	11.1%	1.1	1.1	-1.2%	3.0	3.3	11.1%
Contra Costa	719	1025	42.6%	1.0	1.3	28.8%	5.1	6.7	32.3%
Del Norte	22	23	4.5%	1.4	1.2	-12.0%	4.4	4.6	4.5%
El Dorado	114	151	32.5%	1.1	1.3	18.3%	5.7	6.9	20.4%
Fresno	660	1053	59.5%	1.4	1.9	31.1%	4.8	7.0	45.8%
Glenn	12	23	91.7%	1.7	2.9	67.7%	3.0	5.8	91.7%
Humboldt	110	147	33.6%	1.6	2.1	33.6%	4.6	5.1	10.6%
Imperial	85	109	28.2%	2.7	2.9	7.4%	4.7	5.2	9.9%
Inyo	11	12	9.1%	0.9	0.9	0.7%	2.8	3.0	9.1%
Kern	532	731	37.4%	1.9	2.3	23.1%	5.3	6.4	20.7%
Kings	102	129	26.5%	3.4	3.2	-5.1%	7.3	8.6	18.0%
Lake	41	64	56.1%	1.6	2.7	62.6%	3.7	5.8	56.1%
Lassen	21	31	47.6%	1.5	2.4	59.0%	5.3	7.8	47.6%
Los Angeles	7352	10377	41.1%	1.3	1.6	23.7%	4.6	6.2	35.7%
Madera	106	140	32.1%	3.2	3.4	6.3%	5.3	7.4	39.0%
Marin	86	94	9.3%	0.4	0.4	-6.5%	2.5	2.8	9.3%
Mariposa	9	13	44.4%	1.5	1.9	23.8%	4.5	6.5	44.4%
Mendocino	61	76	24.6%	1.5	1.5	-4.2%	3.2	4.0	24.6%
Merced	140	224	60.0%	2.1	3.0	42.9%	5.2	8.0	54.3%
Modoc	4	5	25.0%	0.8	1.0	25.0%	2.0	5.0	150.0%
Mono	4	6	50.0%	0.8	0.8	-6.3%	2.0	3.0	50.0%
Monterrey	278	343	23.4%	1.6	1.7	9.8%	5.7	6.9	20.9%
Napa	76	100	31.6%	1.1	1.2	6.8%	4.8	5.6	17.0%
Nevada	64	74	15.6%	1.2	1.1	-7.8%	4.6	5.3	15.6%
Orange	1948	2815	44.5%	0.7	0.9	21.1%	3.7	5.3	43.7%
Placer	200	261	30.5%	1.0	0.9	-9.1%	3.9	4.0	0.8%
Plumas	11	13	18.2%	0.8	1.1	28.0%	2.2	2.6	18.2%
Riverside	1420	2004	41.1%	2.4	2.6	11.3%	6.5	8.0	22.0%
Sacramento	1022	1527	49.4%	1.2	1.5	23.5%	5.6	7.6	33.9%
San Benito	36	46	27.8%	3.3	2.9	-12.2%	6.0	9.2	53.3%

San Bernardino	1697	2503	47.5%	2.6	3.4	32.9%	7.6	10.1	32.0%
San Diego	2648	3678	38.9%	1.5	1.8	21.2%	6.8	8.6	25.9%
San Francisco	472	700	48.3%	0.6	0.8	25.3%	3.3	4.9	48.3%
San Joaquin	462	739	60.0%	1.0	1.5	47.6%	4.9	7.5	51.9%
San Luis Obispo	211	247	17.1%	1.2	1.2	0.6%	4.3	4.8	10.3%
San Mateo	466	620	33.0%	0.8	1.0	23.2%	5.3	7.2	36.1%
Santa Barbara	247	323	30.8%	1.3	1.4	13.2%	4.0	4.6	15.8%
Santa Clara	1054	1544	46.5%	0.9	1.2	24.9%	4.6	6.3	38.1%
Santa Cruz	162	188	16.0%	1.2	1.3	6.2%	4.4	4.8	10.1%
Shasta	235	311	32.3%	2.1	2.3	10.6%	6.4	7.8	22.4%
Sierra	0	1	#DIV/0!	0.0	1.0	0.0%	0.0	1.0	#DIV/0!
Siskiyou	28	39	39.3%	1.1	1.1	6.5%	3.1	3.9	25.4%
Solano	418	701	67.7%	2.4	3.5	44.1%	9.5	15.2	60.4%
Sonoma	340	434	27.6%	1.2	1.4	18.4%	5.2	6.4	22.0%
Stanislaus	436	722	65.6%	2.0	3.0	47.8%	6.2	9.6	54.6%
Sutter	58	74	27.6%	1.3	1.4	8.0%	7.3	5.7	-21.5%
Tehama	44	53	20.5%	2.6	2.8	7.8%	4.9	5.3	8.4%
Trinity	14	13	-7.1%	2.8	1.6	-42.0%	4.7	3.3	-30.4%
Tulare	267	332	24.3%	1.8	2.0	11.0%	5.3	6.0	13.0%
Tuolumne	47	59	25.5%	1.3	1.7	25.5%	4.7	5.9	25.5%
Ventura	614	707	15.1%	1.4	1.3	-4.5%	4.9	5.3	8.2%
Yolo	88	140	59.1%	1.0	1.4	42.9%	4.9	6.1	24.5%
Yuba	37	56	51.4%	3.4	3.5	4.1%	5.3	6.2	17.7%
Statewide	26706	37756	41.4%	1.3	1.6	21.8%	5.0	6.7	33.0%

Out of State 750
Out of Country 15

Pharmacist Workforce Estimates

Board of Pharmacy Data -- December 2003

County	Total RPH 2001	Total RPH 2003	% Change	Population 1/1/2001 (DOF Est.)	Population 1/1/2004 (DOF Est.)	% Change	Pharmacists Per 100,000 1/1/2001	Pharmacists Per 100,000 12/1/2003	% Change
Alameda	906	1074	18.5%	1,454,302	1,498,000	3.0%	62	72	15.1%
Alpine	0	0	0.0%	1,193	1,280	7.3%	0	0	0.0%
Amador	21	25	19.0%	34,400	36,850	7.1%	61	68	11.1%
Butte	131	141	7.6%	204,046	212,700	4.2%	64	66	3.3%
Calaveras	14	23	64.3%	38,476	43,350	12.7%	36	53	45.8%
Colusa	8	9	12.5%	18,755	20,100	7.2%	43	45	5.0%
Contra Costa	712	788	10.7%	930,025	1,003,900	7.9%	77	78	2.5%
Del Norte	16	19	18.8%	28,022	28,250	0.8%	57	67	17.8%
El Dorado	100	112	12.0%	152,942	168,100	9.9%	65	67	1.9%
Fresno	461	561	21.7%	805,005	862,600	7.2%	57	65	13.6%
Glenn	7	8	14.3%	27,107	27,750	2.4%	26	29	11.6%
Humboldt	70	70	0.0%	127,633	130,000	1.9%	55	54	-1.8%
Imperial	31	37	19.4%	145,285	156,600	7.8%	21	24	10.7%
Inyo	12	13	8.3%	18,193	18,500	1.7%	66	70	6.5%
Kern	285	318	11.6%	658,935	724,900	10.0%	43	44	1.4%
Kings	30	40	33.3%	131,218	141,400	7.8%	23	28	23.7%
Lake	25	24	-4.0%	55,691	63,200	13.5%	45	38	-15.4%
Lassen	14	13	-7.1%	33,960	34,850	2.6%	41	37	-9.5%
Los Angeles	5525	6302	14.1%	9,884,255	10,103,000	2.2%	56	62	11.6%
Madera	33	41	24.2%	117,074	135,300	15.6%	28	30	7.5%
Marin	201	235	16.9%	249,671	250,200	0.2%	81	94	16.7%
Mariposa	6	7	16.7%	16,143	17,650	9.3%	37	40	6.7%
Mendocino	40	52	30.0%	87,591	89,200	1.8%	46	58	27.7%
Merced	67	75	11.9%	210,138	232,100	10.5%	32	32	1.3%
Modoc	5	5	0.0%	9,794	9,650	-1.5%	51	52	1.5%
Mono	5	8	60.0%	10,914	13,500	23.7%	46	59	29.4%
Monterrey	178	200	12.4%	399,304	421,400	5.5%	45	47	6.5%
Napa	69	85	23.2%	127,005	131,600	3.6%	54	65	18.9%
Nevada	55	69	25.5%	91,097	96,100	5.5%	60	72	18.9%
Orange	2710	3233	19.3%	2,828,351	3,017,300	6.7%	96	107	11.8%
Placer	202	290	43.6%	234,371	292,100	24.6%	86	99	15.2%
Plumas	13	12	-7.7%	20,341	21,100	3.7%	64	57	-11.0%
Riverside	600	761	26.8%	1,522,855	1,776,700	16.7%	39	43	8.7%
Sacramento	869	1051	20.9%	1,209,472	1,335,400	10.4%	72	79	9.5%
San Benito	11	16	45.5%	49,791	57,100	14.7%	22	28	26.8%

San Bernardino	658	730	10.9%	1,689,281	1,886,500	11.7%	39	-0.7%
San Diego	1752	2007	14.6%	2,911,468	3,017,200	3.6%	60	10.5%
San Francisco	774	916	18.3%	801,377	792,700	-1.1%	97	19.6%
San Joaquin	452	490	8.4%	566,628	630,600	11.3%	80	-2.6%
San Luis Obispo	177	206	16.4%	245,191	258,200	5.3%	72	10.5%
San Mateo	591	638	8.0%	730,029	712,400	-2.4%	81	10.6%
Santa Barbara	193	223	15.5%	414,155	414,800	0.2%	47	15.4%
Santa Clara	1136	1332	17.3%	1,736,722	1,731,400	-0.3%	65	17.6%
Santa Cruz	130	142	9.2%	255,021	260,200	2.0%	51	7.1%
Shasta	112	134	19.6%	166,960	175,700	5.2%	67	13.7%
Sierra	1	1	0.0%	3,143	3,520	12.0%	32	-10.7%
Siskiyou	26	34	30.8%	44,184	44,850	1.5%	59	28.8%
Solano	171	199	16.4%	399,026	416,500	4.4%	43	11.5%
Sonoma	281	303	7.8%	450,057	472,700	5.0%	62	2.7%
Stanislaus	216	242	12.0%	441,364	491,900	11.4%	49	0.5%
Sutter	44	52	18.2%	77,878	85,500	9.8%	56	7.6%
Tehama	17	19	11.8%	56,159	58,700	4.5%	30	6.9%
Trinity	5	8	60.0%	13,039	13,450	3.2%	38	55.1%
Tulare	150	168	12.0%	367,961	396,800	7.8%	41	3.9%
Tuolumne	35	35	0.0%	52,953	56,900	7.5%	66	-6.9%
Ventura	453	546	20.5%	756,501	802,400	6.1%	60	13.6%
Yolo	88	98	11.4%	162,928	184,500	13.2%	54	-1.7%
Yuba	11	16	45.5%	60,711	64,800	6.7%	18	36.3%
Total	20905	24256	16.0%	34,336,091	36,143,950	5.3%	61	10.2%

Non-Resident RPH

Out of Country	169
Out of State	5251